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Hollister Incorporated
InCare HOT/ICE Lite Machine

K962537

Safety and Effectiveness Summary

1. Submitter's name, Address and Contact Person

Submitter

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Contact Person

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2. Name of Device:

InCare HOT/ICE Lite Machine

3. Name of Predicate Device(s)

- a. InCare HE500 (K830757)
- b. InCare System 3 (K915196)

4. Description of Device

The InCare HOT/ICE Lite Machine incorporates state of the art technology with solid state electronics. The device is designed to deliver cold therapy to a localized area. This is accomplished by circulating cold water through a plastic blanket or bag that has been secured to the patient's anatomy. The device is intended to be used in an institution or home environment.

5. Statement of Intended Use

The InCare HOT/ICE Lite Machine is intended to provide cold therapy to body surfaces by pumping and circulating chilled water through a plastic bag or plastic blanket that has been secured to the patient's anatomy.

6. Statement of Technological Characteristics of the Device

On the following page is a comparison of the technical specifications of the InCare HOT/ICE Lite Machine and the predicate devices.

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Features/Specs	Proposed device InCare HOT/ICE Lite	InCare HE500 K830757	InCare System 3 K915196
Intended to provide cold therapy to body surfaces	Yes	Yes	Yes
Solution Flow Rates GPH=gallons per hour	4 GPH (nominal)	15 GPH (nominal)	19 GPH (nominal)
Operating Pressure PSI=pounds per square inch	3.5 PSI (nominal)	2.5 PSI (nominal)	4.8 PSI (nominal)
Liquid media	Water / Alcohol	Water / Alcohol	Water / Alcohol
Liquid Capacity	500 ml = 350 ml Water + 150 ml Alcohol	500 ml = 350 ml Water + 150 ml Alcohol	650 ml water/alcohol
Therapy temperature range	50° to 72° F 10° to 22° C	40° to 150° F 4° to 40° C	40° to 150° F 4° to 40° C
Weight	approx 7.1 lbs	approx 20 lbs	32 lbs (approximate)
Power Supply	120VAC, 136 watts, 50/60Hz	115 V, 60 Hz, 3 AMPS	115 VAC, 60 Hz 3 AMPS

7. Performance Testing

The InCare HOT/ICE Lite Machine with a HOT/ICE blanket was evaluated for its ability to cool the test subjects skin as measured by a temperature probe on the skin surface. Skin temperature was recorded over a specific period of time. The results indicated that the InCare HOT/ICE Lite Machine in its ability to reduce patient skin temperature.

8. Conclusion

The InCare HOT/ICE Lite Machine is substantially equivalent to the predicate devices and is safe and effective for its intended use.